

REMARKS

This application is amended in a manner believed to place it condition for allowance.

**Status of the Claims**

Claims 59, 65 and 85-89 are amended substantively.

Support for the amended claims may be found in the originally filed specification, for example, at page 19, line 7 in view of item 7 of Figures 1 and 2.

Claims 59, 61-63, 65, 70, 72, 73, 82, and 85-89 are also amended to correct informalities.

Claims 59-89 remain in this application.

**Claim Objections**

The claims were objected to for including informalities.

Amendments have been made to claims 59, 61-63, 65, 70, 72, 73, 82, and 85-89 as suggested in the Official Action.

Therefore, withdrawal of the objection is respectfully requested.

**Claim Rejections-35 USC §102**

Claims 59-61, 63-65, 67, 69-71, 76-80 and 85-88 were rejected under 35 USC §102(b) as being anticipated by GINN et al.

U.S. 6,626,918 B1 ("GINN"). This rejection is respectfully traversed for the reasons that follow.

The claimed invention

The claimed invention concerns an assembly comprising:

- a suction source;
- an instrument to be positioned in or around a passage surrounded by vascular wall tissue; and
- a stabilizer for stabilizing the vascular wall tissue surrounding the passage.

The stabilizer is provided with a loop of suction nozzles connected to a suction, or vacuum, source. By applying vacuum to the nozzles, the vascular wall tissue is gripped by the stabilizer resulting in fixation of the position of the stabilizer relative to the gripped wall tissue.

The instrument has a head section for performing operations on vascular wall tissue.

The instrument and stabilizer are each provided with a stop. When these stops are in contact with each other they unambiguously define the position of the head section with respect to the position of the loop shape of suction nozzles.

Additionally, the instrument is removably positioned in the stabilizer so that instrument and stabilizer are separable into distinct elements.

The assembly allows one to position the stabilizer relative to the passage and to fixate the stabilizer to surrounding wall tissue in order to maintain the relative position of the stabilizer with respect to the passage. When the instrument is positioned in the stabilizer and the respective stops contact each other, the position of the instrument head (section) with respect to the passage is defined. That is, on the one hand, the relative positions of instrument head and stabilizer are defined by the contacting stops, and, on the other hand, the stabilizer is fixed to the wall tissue/with respect to the passage.

Due to the stabilizer being fixed to, or gripping, the wall tissue, these relative positions are maintained also when the passage/surrounding wall tissue is moving. Such movement might, for example, be caused by the patient making a movement or by the pumping action of the heart. For performing operations on vascular wall tissue it is of great importance to keep the instrument accurately positioned with respect to the location of the operation, in case that the passage is surrounded by the vascular wall tissue. As will be clear the assembly according to the invention allows operations on vascular wall tissue to be performed accurately, reliably and safely.

GINN

GINN discloses an assembly for delivering a vascular closure element for closing an iatrogenic puncture in a blood vessel formed during a diagnostic or therapeutic procedure. See, e.g., column 1, lines 8-11.

Besides the closure element, which is not shown in GINN, the GINN assembly comprises:

- a vascular sheath 12; and
- an obturator 14.

Referring to column 5 lines 23-38, the sheath is a flexible or semi-rigid tube enclosing a lumen 16 extending between the distal and proximal ends of the tube. The distal end 20 has a tapered tip 22 for facilitating atraumatic introduction through the incision 92 - in the skin of the patient - and insertion into the vessel 90. The lumen 16 has a size to accommodate insertion of endoluminal devices therethrough, such as catheters, guidewires and the like. At its proximal end, the sheath is provided with housing for releasably holding the closure element.

Referring to column 5 lines 57-63, the obturator 14 is a flexible/semi-rigid elongate body 28 having, at its proximal end, a handle 34 and, at its distal end, an enlarged distal member 32. The handle 34 is provided with a annular ridge 36 for engagement into a complementary shaped pocket 38 in the sheath

12. When engaging, the ridge 36 and pocket 38 secure the obturator when disposed within the sheath 12.

Referring to column 6 lines 19-23, the sheath 12 includes a plurality of side ports 42 at or near the distal end 20 of the sheath, which ports 42 communicate with the lumen 16. These distal side ports 42 may be disposed circumferentially about a predetermined location with respect to the housing 24.

Referring to column 6 lines 59 - 66, after completion of the procedure, the devices (a catheter, guidewire or otherwise) are be removed from the sheath 12 and the obturator 14 is inserted into the lumen until the distal member 32 of the obturator extends beyond the distal end 20 of the sheath and closes the distal end 20 of the sheath. In this condition the distal ports 42 communicate with the lumen 16 while the distal member 32 of the obturator is distally of the distal side ports 42. Referring to figure 3, the distal side ports 42, the distal member 32 of the obturator, and the distal end 20 of the sheath lie initially inside the blood vessel 98.

Referring to column 6 line 66 - column 7, the GINN assembly functions as follows:

- The sheath 12 and obturator 14 are moved in conjunction with each other up to the distal side ports 42 are adjacent to and not within the vessel 90, i.e. outside the vessel 90 (col. 6 line 66 - col. 7 line 4).

- Saline is directed into flush port 46 to flush blood and other visible body fluid - which is in the lumen 16 of the sheath 12 - from the proximal side port 44(col. 7 lines 4-6).
- Next the sheath 12 and obturator 14 are advanced until the distal side ports 42 enter the blood vessel(col. 7 lines 7-9).
- The internal blood pressure within the vessel 90 - which is greater than the pressure at the flushing port 46 - causes the blood to enter the distal side ports 42, pass through the annular region 48 of the sheath lumen 16, and exit the proximal side port 48(col 7 lines 9-16).
- This blood can be seen at the proximal side port and provides a visual indication that the sheath 12 and obturator 14 are properly positioned with respect to the wall 98 of the blood vessel 90(col. 7 lines 13-18).
- With the sheath properly positioned, the housing 24 is actuated to deliver the closure element (not shown) for closing the vessel/incision(col. 7 lines 19-21).

Thus, the side ports 42 function as positioning means (col. 7 lines 13-18) providing a so called "backbleed" allowing the blood to be seen in order to provide a visual indication that

the sheath 12 and obturator 14 are properly positioned with respect to the wall 98 of the blood vessel 90.

Independent claims 59, 86, 87, 88 and 89 are not anticipated.

The GINN assembly differs from the claimed invention in its design and use.

GINN does not disclose:

- Suction source: Suctioning is not mentioned at all.  
In so far as a medium flows through a part of the assembly, this is clearly due to overpressure and not due to under pressure.
- Suction nozzles.
- A stabilizer for stabilizing vascular tissue (surrounding a passage through this tissue) with respect to any part of the assembly by gripping the vascular wall tissue: According to GINN the assembly is not fixed with respect to the vessel or surrounding wall tissue, but on the contrary it must be movable from the position in figure 3 proximally to the position of figure 4 and subsequently distally to the position of figure 5.
- A head section (of the instrument) for performing operations on vascular wall tissue:

- o the obturator might be considered as an instrument, but the head/distal member 32 of the obturator is neither intended to perform any operation on vascular wall tissue, neither suitable for such an operation;
- o In so far as a catheter, guide wire or other device insertable through the sheath (before the obturator is inserted) is considered as an instrument having a distal head for performing an operation on vascular wall tissue, *it is to be noted that GINN in this respect does not disclose* cooperating stops on the sheath and instrument which together unambiguously define the position of the instrument head with respect to the position of any part - like the side ports 42 - of the sheath.

Thus, GINN fails to anticipate independent claims 59, 86, 87, 88 and 89, as well the dependent claims 60, 61, 63-65, 69-71, 76-80 and 85.

Therefore, withdrawal of the rejection is respectfully requested.

**Claim Rejections-35 USC §103**

Claims 62, 66, 68, 72-75 and 81-84 were rejected under 35 U.S.C. §103(a) as being unpatentable over GINN. Claim 89 was



rejected under 35 U.S.C. §103(a) as being unpatentable over GINN in view of BRUMBACH U.S. 6,033,375 ("BRUMBACH"). This rejection is respectfully traversed for the reasons below.

The features of independent claims 59, 86, 87, 88 and 89 are not obvious over GINN

GINN discloses an assembly for visually controlling the depth that a sheath is inserted into the body/a vessel. When the sheath region with the side ports 42 is outside the vessel, no blood will flow into the sheath and consequently one will not see blood. When this sheath region with side ports lies inside the blood vessel, blood will flow into the sheath and will become visible at the proximal end of the sheath.

The object of the GINN device is to determine the position of the vessel wall accurately in order to be able to place subsequently a closure element. As described above in response to the anticipation rejection, it is an indispensable requirement for the function of the GINN device that the sheath and obturator are movable in conjunction with respect to the vascular tissue (see also column 6 line 66 to column 7 line 21).

Thus, it would have been unobvious to fixate the sheath of GINN with respect to the surrounding wall tissue by a suction source, as GINN teaches away from fixating its sheath with respect to any tissue.

Further, assuming one would apply a vacuum on the proximal port 44 of GINN it is to be noted that:

- This vacuum would draw in air from the surrounding via the proximal end 18 of the sheath 12, which is only fluid-tight but not gas tight as it is designed to allow insertion of a device, like a catheter, guide wire or obturator (see col. 5 line 65 - col. 6 line 2) and consequently the distal side ports 42 would not suck tightly to tissue as the vacuum pressure is not prevailing there anymore. Thus, it is not possible at all to provide a vacuum at the distal ports 42 of GINN.
- Assuming it would be possible to apply a vacuum at the distal side ports 42 of GINN, this would cause great discomfort for the patient as well as increasing the wound at the incision with the result increase of the healing time (which is already a problem with these kind of device). This would be highly undesirable.
- Assuming it would be possible to apply a vacuum at the distal side ports 42 of GINN, this would result in drawing in blood not only when the ports 42 are inside the blood vessel 98 but also when the ports are (just) outside the blood vessel. This would be

highly undesirable, as the aim of such assemblies is to prevent bleeding.

Thus, GINN clearly teaches away from applying any vacuum at the suction ports.

BRUMBACH fails to remedy the shortcomings of GINN for reference purposes.

BRUMBACH was offered for teaching a set screw for fixing two instruments with respect to each other such that rotational movement is prevented between them. However, regardless of the ability of BRUMBACH to teach that for which it is offered BRUMBACH does not remedy the shortcomings of GINN for reference purposes.

Specifically, as discussed above, it is an indispensable requirement that the sheath and obturator of GINN are movable in conjunction with respect to the vascular tissue. Thus, the use of the set screw would be contrary to the teachings of GINN.

Therefore, neither GINN nor GINN combined with BRUMBACH renders obvious the claimed invention, and the withdrawal of obvious rejections with respect to claims 62, 66, 68, 72-75, 81-84 and 89 is respectfully requested.

**Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our credit card which is being paid online simultaneously herewith for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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